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November 16, 2016

Health Care Services Corporation
Medical Policy Division
300 E. Randolph Street
Chicago, IL 60601

RE: Comments to Draft Policy SUR712.036 – Lumbar Spinal Fusion

Dear Medical Director:

On behalf of the International Society for the Advancement of Spine Surgery (ISASS), I am writing to submit comments to Draft Policy SUR712.036 – Lumbar Spinal Fusion.

ISASS is a global, scientific and educational society organized to provide an independent venue to discuss and address the issues involved with all aspects of basic and clinical science of motion preservation, stabilization, innovative technologies, MIS procedures, biologics and other fundamental topics to restore and improve motion and function of the spine.

Specifically, ISASS is concerned that HCSC deems lumbar spinal fusion not medically necessary to treat degenerative disc disease (DDD). As part of our lumbar fusion policy statement, ISASS developed the following indications/criteria for lumbar fusion to treat DDD based on a thorough review of the literature at the time the policy was developed:

Degenerative Disk Disease (DDD) - Lumbar spinal fusion surgery is medically indicated – at a maximum of two levels – when all of the following conditions are met:

- a) The patient presents with clinically important pain and disability consistent with diskogenic pain.

- b) MRI (or other imaging) demonstrates morphological disk degeneration.
- c) The patient has not shown sufficient improvement from a minimum of 6 consecutive months of structured conservative medical management (including at least pain medication, activity modification, and daily exercise), with adequate patient compliance.
- d) The patient has then subsequently not shown sufficient improvement from a program of intensive multidisciplinary rehabilitation, (with a minimum volume of 80 hours of on-site treatment during a 2-4 week period, including a cognitive- behavioral component), if such a program is locally available and covered by the patient's insurance.
- e) The patient has been appropriately screened for possible mental illness and/or substance abuse issues, and if present has undergone professional treatment for these issues.
- f) The patient is not currently involved in an ongoing litigation case related to his or her back. (This does not refer to "worker's compensation".)
- g) The patient is age 25-65.
- h) The patient is not pregnant.
- i) Either provocative discography (with concordant pain and negative adjacent levels) or magnetic resonance spectroscopy (MRS) has provided corroborating evidence that the patient's pain is likely due to the disk degeneration observed on imaging, and the two are not merely an unrelated coincidence.

Since the ISASS lumbar fusion policy was developed, Zigler & Delamarter (2013)¹ examined outcomes of patients assigned to the lumbar fusion treatment arm of the randomized, controlled, multicenter FDA clinical trial that evaluated total disc replacement (ProDisc-L) compared with circumferential fusion. The major inclusion criteria were as follows: skeletally mature individuals with functionally disabling radiographically proven DDD at one vertebral level between L3 and S1 (by plain radiographs, magnetic resonance imaging scan, computed tomography scan, or discography), in whom conservative treatment for a minimum of six months had failed, who had back and/or leg (radicular) pain, and who had a minimum ODI score of 40% impairment or greater. The main exclusion criteria were as follows: patients with greater than grade I spondylolisthesis, previous lumbar fusion, T score on dual-energy x-ray absorptiometry scan worse than -1.0, or clinically relevant facet joint degenerative disease. A total of 80 patients who failed at least six months of non-operative treatment were randomized to fusion and treated surgically. 75 of these patients were treated on protocol and were followed for five years following the fusion surgery.

¹ Zigler JE, Delamarter RB. Does 360° lumbar spinal fusion improve long-term clinical outcomes after failure of conservative treatment in patients with functionally disabling single-level degenerative lumbar disc disease? Results of 5-year follow-up in 75 postoperative patients. *Int J SpineSurg.* 2013 Dec 1;7:e1-7.

The authors found that patient outcomes support 360° fusion surgery as a predictable and lasting treatment option to improve pain and function in properly selected patients with mechanical DDD. These improvements occurred dramatically immediately after surgery and were maintained through five years follow-up, with 98% of patients available at two years and 75% of patients available at five years. The results show patients treated with fusion experienced improvements in:

- Oswestry Disability Index (ODI) Scores- Patients experienced immediate and significant improvement compared with their baseline ODI scores, and this improvement persisted out to five years, at all times remaining statistically significantly better than their status after nine months of conservative treatment.
- SF-36 Physical Component Summary (PCS) - At two years, 70.0% of fusion patients had maintenance or improvement in SF-36 PCS scores. At five years, 72.6% of fusion patients had maintenance or improvement in SF-36 PCS scores compared with baseline.
- Neurologic Success - At two years, the fusion group showed success in 81.4% (57 of 70 patients). Compared with two years, the percentage of patients achieving overall neurologic success at five years increased in fusion patients (43 of 48 patients, 89.6%). Of the 13 fusion patients who were considered to have neurologic failure at two years, six were found to have neurologic success at five years.
- VAS Pain Scores - Fusion patients showed statistically significant improvements in VAS pain scores at both two years and five years compared with baseline. The mean percent improvements in VAS pain scores were similar at the two-year and five-year follow-up visits.
- Recreational Activity Status - At baseline, only 49.3% of 75 fusion patients reported that they engaged in recreational activities. At two years, the recreational status improved, with 78.3% of 69 fusion patients able to enjoy recreational activities. At five years, 90.0% of 50 fusion patients were able to return to recreation.
- Narcotic Use - At the time of surgery, 76% of fusion patients had used narcotics as a form of prior conservative treatment. The percentage of patients taking narcotics decreased from baseline at two years (42.5% of 70 fusion patients) and remained diminished at five years (40.0% of 50 fusion patients).

Secondary surgeries at the index level occurred in 12% (9 patients) by the end of the five-year study and severe or life-threatening adverse events were reported at 0.39 per patient. The authors note that proper patient selection requires strict adherence to inclusion/exclusion criteria, a firm diagnosis of anterior column discogenic pain origin, and a failure of at least six months of conservative therapy.

These results add to the body of high-quality scientific evidence showing positive patient outcomes following lumbar fusion to treat DDD in properly selected patients. ISASS requests HCSC review the current literature on lumbar fusion to treat DDD in addition to our policy

statement and update Policy SUR712.036 to allow for coverage of lumbar fusion to treat DDD in properly selected patients.

Thank you for your time and consideration of our comments. Please do not hesitate to contact Liz Vogt, ISASS Director of Health Policy & Advocacy by email at liz@isass.org or by phone at (630) 375-1432 with questions or requests for additional information. We look forward to establishing a continued partnership with HCSC so together we can advocate for quality patient care and superior patient outcomes.

Sincerely,

Morgan P. Lorio, MD, FACS
Chair, Coding and Reimbursement Task Force
International Society for the Advancement of
Spine Surgery

Jack E. Zigler, MD
Member, Board of Directors
International Society for the Advancement of
Spine Surgery

Enclosure: ISASS Lumbar Fusion Policy Statement